4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1967]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biosimilars User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0719. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Biosimilars User Fee Program

OMB Control Number 0910-0718--Revision

This information collection supports FDA's Biosimilars User Fee Program. The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) amended the Public Health Service Act (PHS Act) to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, allows a company to apply for licensure of a biosimilar or interchangeable biological product (351(k) application). The BPCI Act also amended section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) to include 351(k) applications as a type of application under "human drug application" for the purposes of the prescription drug user fee provisions.

The Biosimilar User Fee Act of 2012 (BsUFA) authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development (BPD). BsUFA was reauthorized for an additional 5 years in August 2017 (BsUFA II). We developed the guidance entitled "Assessing User Fees Under the Biosimilar User Fee Amendments of 2017" to assist industry in understanding when fees are incurred and the process by which applicants can submit payments. The guidance also explains how respondents can request discontinuation from the BPD program as well as how respondents can request to move products to the discontinued section of the biosimilar list. Finally, the guidance provides information on the consequences of failing to pay BsUFA II fees as well as processes for submitting reconsideration and appeal requests. The guidance is available on the FDA website at: https://www.fda.gov/media/134567/download. The guidance was issued consistent with our good guidance practice regulations in § 10.115 (21 CFR 10.115), which provide for public comment at any time.

We also developed Form FDA 3792, the Biosimilars User Fee Cover Sheet, which is submitted by each new BPD entrant (identified via a new meeting request or investigational new drug (IND) submission) and for new biologics license applications (BLAs). Form FDA 3792

requests the minimum necessary information to identify the request, to determine the amount of the fee to be assessed, and to account for and track user fees. The form provides a cross-reference of the fees submitted for an activity with the actual submission or activity by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research to initiate the administrative screening of biosimilar biological product INDs and BLAs and to account for and track user fees associated with BPD meetings.

In addition to Form FDA 3792, the information collection includes an annual survey of all BsUFA II participants designed to provide information to FDA of anticipated BsUFA II activity in the upcoming fiscal year. This information helps FDA set appropriate annual BsUFA II fees.

For efficiency of Agency operations, we are consolidating related information collection currently approved in OMB control number 0910-0719. Specifically we are including our current commitment goals as set forth in the document "BsUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022," which represents the product of FDA discussions with regulated industry and public stakeholders, as mandated by Congress. The document, referred to as the "BsUFA II letter," is available on our website at: https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf. The performance and procedural goals specified in the BsUFA II letter apply to aspects of the biosimilar biological product review program that are important for facilitating timely access to safe and effective biosimilar medicines for patients. Among those considerations is providing feedback to requests from regulated industry. Each year, FDA review staff participate in many meetings with requesters who seek advice relating to the development and review of a biosimilar or interchangeable product. Because these meetings often represent critical points in the regulatory and development process, it is important that there are clear procedures for the timely and effective conduct of such meeting. Accordingly, we issued draft guidance, "Formal

Meetings Between the FDA and Sponsors or Applicants of BsUFA Products," available on our website at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-fda-and-sponsors-or-applicants-bsufa-products-guidance-industry. The guidance was issued consistent with Section I, Part 6 of the BsUFA II letter (see p. 25), and with our good guidance practice regulations in § 10.115, which provide for public comment at any time. The guidance provides procedural instruction helpful to respondents and helps us reach what we believe is a more accurate burden estimate for the information collection.

Also available from our website is our Biosimilars Action Plan (BAP), which discusses key actions the Agency is taking to encourage innovation and competition among biologics and the development of biosimilars. The BAP builds on progress in implementing the approval pathway for biosimilar and interchangeable products, and provides interested persons with updates and resource material.

In the *Federal Register* of September 17, 2021 (86 FR 51900), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden

FDA Form; Survey	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Biosimilar User Fee Cover Sheet (Form FDA 3792)	60	1	60	0.5 (30 minutes)	30
Annual Survey	60	1	60	1	60
Request for discontinuation from BPD program	10	1	10	1	10
Request to move products to discontinued section of the Biosimilar List	5	1	5	0.5 (30 minutes)	2.5
Biosimilar product applications (351(k)(2)(A))	4	2.25	9	860	7,740
Interchangeable product applications (351(k)(2)(B))	2	1	2	860	1,720
Patent infringement notifications	4	2.25	9	2	18
Formal Meetings Guidance for Industry Recommendations	69	2.30	159	21.42	3,405
Total			314		12,985.5

In anticipation of increased participation in the BPD program, we have adjusted our estimate to reflect an increase in the number of respondents since last OMB review. We have also made adjustments to reflect information collection consolidated from OMB control number 0910-0719. We invite comment on our estimates and assumptions.

Dated: December 15, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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